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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,710	04/14/2004	Chih-Ping Liu	55600-8014.US00	7146

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EXAMINER	
MOSHER, MARY	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/824,710	LIU ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/7/04, 8/12/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/910,406.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

JOD

DETAILED ACTION

Response to Amendment

The amendments filed May 7 2004 and August 12 2004 are objected to under 35 U.S.C. 132(a) because they introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the incorporation by reference of applications 09/910406, 60/219128, and JP 317160. The claim to benefit of these applications is permissible; however, since they were not incorporated by reference on the filing date, the incorporation by reference constitutes new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Priority

Receipt is acknowledged of papers filed under 35 U.S.C. 119 (a)-(d) based on an application filed in Japan on October 17, 2000. Applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath, declaration or application data sheet does not acknowledge the filing of any foreign application. A new oath, declaration or application data sheet is required in the body of which the present application should be identified by application number and filing date.

In addition, the first paragraph of the specification should state that application 09/910406 claims benefit of the foreign application; this application cannot claim benefit directly, since there has been more than 1 year between the foreign application date and this application's filing date.

Claim Rejections - 35 USC § 112

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 is confusing in reciting "said oral administration is to the intestinal tract of the subject," since the intestine is not the mouth.

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 1 is drawn to a method for up-regulating the blood IL-10 of a human, comprising orally administering interferon-tau to produce a measurable increase in blood IL-10, then continuing to administer the IFN-tau until achieving a desired clinical endpoint. Dependent claims specify that the endpoint is alleviation of autoimmune disease symptoms, reduction in symptoms (or blood viral titer) for a viral infection, or reduction in cancer symptoms. However, in the working examples, similar doses of IFN-tau produced different results in different groups of patients: compare the lowest doses in the HCV study with the highest 2 doses in the MS study; the HCV patients apparently showed some increase in blood IL-10 level, while the MS patients did not. Therefore, the general guidance in the specification as to what dose to use is not sufficient to indicate the dose necessary for achieving increased IL-10 in the wide variety of disease conditions recited in the claims. Furthermore, there is no working example that demonstrates achieving a desired endpoint, the data are strictly limited to analysis of

serum cytokine levels. There does not appear to be a consensus in the art that increasing the blood IL-10 level produces a beneficial clinical result for any of the disease conditions discussed in the specification or recited in the claims. The reviews by Li et al (World Journal of Gastroenterology 10:620-625, 2004) and van Roon et al (Journal of Rheumatology 30:648-51, abstract only cited) indicate that clinical studies of IL-10 therapies have shown little efficacy. Considering the broad scope of the claims, the state of the art, the limited teachings in the specification, the absence of working examples for the method as claimed (e.g. absence of clinical endpoints), and the recognized difficulty in treating the disease states recited in the claims, it is concluded that undue experimentation would be required to enable the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-7, rejected under 35 U.S.C. 103(a) as being unpatentable over Soos et al US 6060450. Soo teaches and claims a method for treating an autoimmune disease comprising administering to the subject a pharmaceutically effective amount of tau interferon. Claimed methods include administering bovine or ovine tau interferon, administering orally, and treating several of the human diseases listed in applicant's claim 7. Soos teaches in column 14, lines 25-27, doses of about 5×10^8 units/day or more can be used. Therefore it would have been within the ordinary skill of the art to combine the teachings of Soos to reach an oral dose of 5×10^8 units/day or more for treating one of the human autoimmune conditions, and to maintain the dose until achieving a desired outcome. Although the reference is silent upon blood levels of IL-10, the teachings of the reference would inherently result in this outcome, if indeed there is a cause-and-effect relationship between oral IFN-tau and blood IL-10 level. Therefore, in the absence of unexpected results, the invention as a whole is seen as prima facie obvious.

Claims 1-3, 5, 6, 16, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soos et al (Journal of Immunology 169:2231-22235, 2002). In making this rejection, applicant is denied the benefit of application 09/910406, because the application does not describe regulation of blood interleukin 10 level, or treatment of autoimmune diseases. Soos teaches that a combination of oral IFN-tau and glatramer acetate has a synergistic effect upon a mouse model for multiple sclerosis. Soos

explicitly suggests the treatment for multiple sclerosis. It would have been within the ordinary skill of the art to modify and optimize the dosage for a human, with reasonable expectation of success. The invention as a whole is therefore prima facie obvious, absent unexpected results.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 8, 12, 13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-26 of copending Application No. 09/910406. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to treatment of HCV infection by orally administering IFN tau in similar amounts.

Claims 1-13, 16-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/825382. Although the conflicting claims are not identical,

they are not patentably distinct from each other because both sets of claims involve treating the same conditions with similar amounts of oral IFN tau, alone or in combination with other pharmaceuticals.

Claims 1-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/825457. Although the conflicting claims are not identical, they are not patentably distinct from each other because they involve treating the same conditions with similar amounts of oral IFN-tau, alone or in combination with other pharmaceuticals.

Claims 16-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 10/884741. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to treating similar conditions with similar doses of oral IFN tau in combination with other pharmaceuticals.

Claims 1-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,2, 5-9, 12, 25, 30-32 of copending Application No. 11/040706. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to treating similar conditions with similar doses of oral IFN tau, alone or in combination with other pharmaceuticals.

Claims 1-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 11/078608. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the claimed treatments is that the copending application requires testing serum levels of several cytokines during the treatment. The instant specification teaches the same tests, and the instant claims require "a measurable increase". Measuring the amount and requiring "a measurable increase" are seen as obvious variations.

All of the above are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9/26/05

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER